

REMARKS

Claims 1-26 were pending in the present application. Claims 4, 5, 7-9, 17, 18, and 20-22 have been indicated as being withdrawn, as being drawn to a non-elected invention. Claims 1 and 14 have been amended herein. No new matter has been added. Upon entry of the present amendment, claims 1-26 will remain pending.

Applicants acknowledge the Office's line drawn through references 13-15 of the IDS filed March 11, 2009 with the notation by the Office that the references are "not publicly available" written in the margin. Applicants filed a "Notice of Co-Pending Applications" on March 11, 2009 in which Applicants brought to the attention the existence of two related, co-pending applications (e.g., USSN 10/524,082 and USSN 11/568,673), thus complying with Rule 56. In the same IDS filing on March 11, 2009, Applicants brought to the Office's attention three office actions collectively issued in the two co-pending applications, thus further complying with Rule 56 and case law regarding the same (i.e., *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003)). Thus, Applicants respectfully request that the Office recognize Applicants' compliance with Rule 56 by considering references 13-15 of the IDS filed March 11, 2009. Indeed, the section of the IDS under which references 13-15 are listed is entitled "NON-PATENT LITERATURE DOCUMENTS" -- this section is not limited to "publicly available" documents.

I. The Claimed Invention Is Novel

Claims 1-3, 6, 10-16, 19, and 23-26 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by International PCT Publication WO 2004/014423 (hereinafter, the "Charlton reference"). Applicants traverse the rejection and respectfully request reconsideration thereof because the Charlton reference does not teach every feature recited in the rejected claims.

Although the Charlton reference reports treatment of an "infection", it does not describe or even suggest that administration of the antibodies would cause autolysis in a population of bacteria. Further, the Charlton reference does not disclose the desired effect of autolysis in bacteria. In contrast, the Charlton reference merely suggests to the skilled person that antibodies to lactone or lactone-derived signal molecules are "bacteriostatic." There is nothing, however, in the Charlton reference to suggest that the antibodies are bacteriocidal. It is well established in the

art that treatment of bacterial infection can encompass the use of bacteriostatic or bacteriocidal compositions (or combinations thereof). The different classes of compositions are well characterised and evidence suggesting the bacteriostatic effect of a composition in no-way suggests that a composition consisting of the same components would have a bacteriocidal effect on a population of bacteria. Therefore, it is clear that the present application discloses a new technical effect such that the composition finds a new method. To emphasize this point even more, Applicants have amended claims 1 and 14 to further recite the desire to induce a collapse in bacterial cell numbers, support for which can be found at, for example, the paragraph bridging page 8 and 9 of the underlying PCT application, whereby Applicants teach the desired outcome of a collapse in bacterial cell numbers.

Thus, the Charlton reference does not teach every feature recited in claims 1-3, 6, 10-16, 19, and 23-26. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be withdrawn.

II. Obviousness-Type Double Patenting

A. U.S. Serial No. 10/524,082

Claims 1-3, 6, 10-16, 19, and 23-26 are provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-53 of co-pending application Serial No. 10/524,082. Applicants traverse this rejection and respectfully request reconsideration because the claimed subject matter of the present application is not an obvious variant of the subject matter presently claimed in U.S. Serial No. 10/524,082.

As a preliminary matter, it does not appear from the records posted in PAIR that U.S. Serial No. 10/524,082 ever had 53 claims. In addition, an obviousness-type double patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. §103. *In re Braithwaite*, 154 U.S.P.Q. 29, 34 (C.C.P.A. 1967) and *In re Longi*, 225 U.S.P.Q. 645, 648 n.4 (Fed. Cir. 1985). Thus, under the law, the pivotal question in an obviousness-type double patenting analysis is: Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? *In re Vogel*, 164 U.S.P.Q. 619 (C.C.P.A. 1970). If the answer to this question is no, there can be no double patenting. In making this analysis, then, the proper inquiry is as taught in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). See, M.P.E.P.

§804. No such analysis has been carried out by the Office.

Further, the presently pending claims in U.S. Serial No. 10/524,082 (see, claim 11 of the claim set in response filed August 19, 2009) recite a “method of screening a naïve human phage display library for an anti-bacterial monoclonal antibody” in which a homoserine lactone molecule of general Formula I is conjugated to a first carrier molecule “to generate an enriched library, and screening said enriched library against the homoserine lactone molecule conjugated to a second, different carrier molecule to identify a monoclonal antibody that specifically binds to the free soluble form of the homoserine lactone or a C₁-C₁₀ saturated or unsaturated carboxylic acid derivative thereof from the enriched library in the presence of conjugated derivatives thereof.” No explanation is provided by the Office why Applicants’ claims of the present application are obvious variants of claim 11 of U.S. Serial No. 10/524,082.

Claim 35 of U.S. Serial No. 10/524,082 presently recites “A method for the treatment of a bacterial infection in a subject comprising administering to said subject a monoclonal antibody identified according to the method of claim 11.” Again, the Office provides no explanation why Applicants’ claimed method of causing autolysis of a population of gram-negative bacteria (see, claim 1 of the present application) is an obvious variant of the method of screening set forth in claim 11 of U.S. Serial No. 10/524,082. To the extent that the Office takes the position that claim 14 of the present application is an obvious variant of the subject matter of claim 35 of U.S. Serial No. 10/524,082, then Applicants remind the Office that a determination that one set of claims “encompasses” another is not the appropriate inquiry. The following quotation from *In re Kaplan*, 229 U.S.P.Q. 678 (Fed. Cir. 1986) is instructive:

By domination we refer ... to that phenomenon ... whereunder one patent has a broad or “generic” claim which “reads on” an invention defined by another narrower or more specific claim in another patent, the former “dominating” the latter because the more narrowly claimed invention cannot be practiced without infringing the broader claim ... In possibly, simpler terms, one patent dominates another if a claim of the first patent reads on a device built or process practiced according to the second patent disclosure. This commonplace situation is not, *per se*, double patenting as the board seems to think. (citations omitted).

Thus, that some of Applicants’ methods claimed in the present patent application may have features that may also meet features of claims in a co-pending patent application is not grounds

for an obviousness-type double patenting rejection. It may simply be a case of one patent application dominating another patent application. Domination by itself cannot support a double patenting rejection. Thus, the obviousness-type double patenting rejection is misplaced.

In view of the foregoing, Applicants respectfully request that the obviousness-type double patenting rejection in view of co-pending application Serial No. 10/524,082 be withdrawn.

B. U.S. Serial No. 11/568,673

Claims 1-3, 6, 10-16, 19, and 23-26 are provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-45 of co-pending application Serial No. 11/568,673. Applicants traverse this rejection and respectfully request reconsideration because the claimed subject matter of the present application is not an obvious variant of the subject matter presently claimed in U.S. Serial No. 11/568,673.

Again, as observed above, the proper inquiry taught in *Graham v. John Deere Co.*, has not been carried out by the Office. Further, no explanation is provided by the Office why Applicants' claims of the present application (i.e., "method of screening a naïve human phage display library for an anti-bacterial monoclonal antibody..." and "method for the treatment of an infection of gram-negative bacteria in a subject...") are obvious variants of, for example, claim 1 of U.S. Serial No. 11/568,673 which recites a "method of preventing or inhibiting biofilm formation by a population of bacteria..." Again, simply because the claims of the present application "encompasses methods of administering antibodies immunoreactive with Formula I homoserine lactone" is not the appropriate inquiry. It may simply be a case of one patent application dominating another patent application. As stated above, domination by itself cannot support a double patenting rejection. Thus, the obviousness-type double patenting rejection is misplaced.

In view of the foregoing, Applicants respectfully request that the obviousness-type double patenting rejection in view of co-pending application Serial No. 11/568,673 be withdrawn.

III. The Claimed Invention Is Sufficiently Enabled

Claims 13 and 26 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. The Office mistakenly asserts that “the specification lacks complete deposit information for the deposit of NCIMB-41167, NCIMB-41168, NCIMB-41169, and NCIMB-41170...” (see, page 2 of the Office Action). Applicants traverse the rejection and respectfully request reconsideration thereof.

Applicants direct the Office’s attention to pages 32-39 of the present application (referring to the published International Application No. PCT/GB2005/001108) in which the “Indications Relating To A Deposited Microorganism” (hereinafter, “Indications”) under PCT Rule 13bis are presented for each of NCIMB-41167, NCIMB-41168, NCIMB-41169, and NCIMB-41170. These Indications reflect that NCIMB-41167, NCIMB-41168, NCIMB-41169, and NCIMB-41170 have been deposited with NCIMB Ltd. of Scotland, an International Depository Authority, on March 18, 2003. In addition, the accompanying “Budapest Treaty On The International Recognition Of The Deposit Of Microorganisms For The Purposes Of Patent Procedure” for each of the deposits have been executed by a person having power to represent the International Depository Authority. Applicants submit that this documentation is sufficient.

Thus, there is no reason to believe that one skilled in the art would be required to perform any amount of undue experimentation to make and use the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

IV. The Claims Are Clear And Definite

Claims 1 and 14 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Office asserts that there is “no way for the person of skill in the art to ascribe a discrete and identifiable definition” to the phrase “lactone derived signal molecule” because it is allegedly “unclear if the protein is undergoing any kind of chemical modification as implied by the recitation of ‘derived’” (see, page 4 and 5 of the Office

Action). Applicants traverse the rejection and respectfully request reconsideration because the claims are clear and definite.

Persons of ordinary skill would have no difficulty in determining whether a particular antibody was to a “lactone-derived signal molecule.” Accordingly, the claims are definite within the meaning of §112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Indeed, the phrase “lactone-derived signal molecule” is quite clear to those skilled in the art. For example, it is clear that the lactone-derived signal molecule would be a signal molecule of the lactone family that is secreted by the population of gram-negative bacteria. Further, the lactone-derived signal molecule clearly performs the function of a signal molecule in quorum sensing. Persons of ordinary skill would have no difficulty in determining whether a particular signal molecule meets these criteria. The Office provides no credible reasoning why one skilled in the art would be unable to determine whether any particular signal molecule is a lactone-derived signal molecule.

Thus, in view of the foregoing, claims 1 and 14 are clear and definite. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

V. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Office is invited to contact Applicants’ undersigned representative at 610.640.7859 if there are any questions regarding Applicants’ claimed invention.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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